

REMARKS/ARGUMENTS

Claims 1-9 and 13-15 are pending. Claims 1-9 and 13-15 are rejected. Claims 11-12 and 16-29 were withdrawn in response to the restriction requirement. New claims 30-35 are added. The amendments to the claims should not be construed as acquiescence in the rejection.

Support for the amendment of claim 1 can be found, e.g., at page 4, paragraph 2, and the table of page 13. Support for new claim 30 can be found, e.g., in original claim 2. Support for new claims 31 and 32 can be found, e.g., in the table of page 13. The new independent claims combine claim 1 with elements from previous dependent claims. Support for new claim 33 can be found, e.g., in original claims 1 and 2. Support for new claim 34 can be found, e.g., in original claims 1, 4, and 9. Support for new claim 35 can be found, e.g., in original claims 1, 10, and 11.

Species Election

Traverse is maintained. It is noted that "Carnallite", as the term is used in the specification (see Table on p. 13), does contain a combination of the salts recited in claim 1.

Claim Objections

Grammatical changes to claims 1 and 3 have been requested by the Examiner. Claims 1 and 3 have been amended to correct grammatical errors.

35 U.S.C. § 112 Enablement

The Examiner has rejected claims 1-9 and 13-15 as not providing enablement for a composition for preventing oral disease. The statement of intended use in which "preventing" occurs is not limiting in a composition claim and thus has been deleted as redundant. Hence, the rejection is moot.

35 U.S.C. § 112 Indefiniteness

The Examiner has rejected claims 2, 4, 14, and 15 as indefinite. It appears that the Examiner meant to include claim 1 as part of this rejection, as this claim is discussed in this section as well.

Applicant has amended claim 1 in response to this rejection by rephrasing claim 1 to read "...comprising an active agent, wherein the active agent contains at least 70% by weight monoterpenes with three unsaturations..." This amendment clarifies the composition of the active agent.

Applicant has amended claim 2 for clarification by breaking the claim into a first section and a new claim 30.

Applicant has amended claim 4 to clarify the composition of the active agent.

Claims 14 and 15 have been amended to clarify that the percentages recited are of the composition.

35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 3, and 13 as anticipated by Huzinec in light of Kekelidze. The Examiner says that Huzinec disclosed a chewing gum which contained calcium chloride, gum base, and lemon oil. The Examiner says that Kekelidze showed three varieties of lemons which all contained greater than 70% monoterpenes with three unsaturations, and thus, it is deemed that lemon oil inherently contains a 70% content of monoterpenes with three unsaturations. Applicant traverses the rejection insofar as it might be applied to the amended claims.

Claim 1 has been amended to specify that the composition contains at least two salts selected from the group consisting of MgBr_2 , MgCl_2 , NaCl , KCl , and CaCl_2 . Applicant has discovered that the inclusion of multiple salts, in combination with various monoterpenes, provides a synergistic effect on improving oral health. For example, the beneficial properties of the use of multiple salts are disclosed in Example 5 of the specification, starting on p.22. This example provides data showing that Carnallite (defined on p.13 as a mixture of MgBr_2 , MgCl_2 ,

NaCl, KCl, and CaCl_2) provides a significant improvement in the periodontal index of oral health as compared to the use of only single salts (see Table 3, p. 22). The specification also shows that Carnallite (as defined as a mixture of MgBr_2 , MgCl_2 , NaCl, KCl, and CaCl_2) in combination with limonene provides a synergistic effect on inhibiting the growth of *L. major* bacteria compared to Carnallite or limonene alone (see Table 1, p.17).

Huzinec discusses a chewing gum coating which contains CaCl_2 , gum base, and lemon oil. Huzinec discusses several calcium salts as possible components of the gum coating (see column 2, lines 42-48), pointing out that calcium is a necessary component of the invention (see column 1, line 56- column 2, line 11). The calcium salts are included to produce a chewing gum coating that is not flaky (column 1, line 56- column 2, line 11). Lemon oil is discussed in Huzinec solely as a flavoring additive (column 3, lines 50-65). Huzinec does not mention other salts required by amended claim 1 except to state that MgCl_2 is specifically not a part of the invention because use of this salt produces an undesirable gum coating (column 2, lines 7-11).

Kekelidze discusses the composition of essential oils of citrus varieties.

As amended, the claims are not anticipated by Huzinec because Huzinec does not disclose a composition containing at least two salts from the group recited in claim 1. It would not have been obvious to modify Huzinec's teaching to include a second salt from the group recited in claim 1 because Huzinec provides no indication that additional salts (other than calcium salts) would be useful for the intended purpose of producing a chewing gum coating that is not flaky. Huzinec specifically mentions MgCl_2 as unsuitable for use in chewing gum coatings. Huzinec also provides no indication that other salts recited in claim 1 would be useful for any other purpose in the composition, and particularly does not recognize the synergistic effects of multiple salts and monoterpenes as an anti-microbial agent. For these reasons, it is submitted that the amended claims are neither anticipated nor obvious over Huzinec.

35 U.S.C. § 103(a): Huzinec, Delli Santi and Kekelidze

The Examiner has rejected claims 1-9 and 13-15 as obvious over Huzinec in view of Delli Santi and Kekelidze. Huzinec is applied as above. Kekelidze is cited as showing that a particular variety of lemon, a Novo lemon, provides lemon oil containing 89% limonene. Delli Santi is cited as teaching that limonene improves flavoring, masks the flavor of phenols and has anti-bacterial effects. The Examiner takes the view that it would have been obvious to use Novo lemon oil containing at least 89% limonene, as disclosed by Kekelidze, in Huzinec's composition for the benefit of improved flavor and improved anti-bacterial activity as disclosed by Delli Santi. This rejection is respectfully traversed as applied to the amended claims.

Delli Santi discusses an oral rinse, dentifrice, or oral gel composition that comprises 0.01-5% by weight of a citrus flavor, 0.01-5% by weight of a phenolic, and a carrier that consists of mixtures of water and ethanol. Delli Santi does not propose including any of the salts recited in claim 1.

The present claims would not have been obvious over the combination of the above three references for at least the same reason as that discussed for Huzinec alone. That is, none of the additional references remedy Huzinec's lack of disclosure of at least two salts from the group recited in claim 1. Kekelidze is cited only for its discussion of the composition of lemon oils, and provides no information about salts to use with lemon oil. Delli Santi is cited only with respect to flavoring and bacteriostatic properties of limonene, and again provides no information about the salts recited in amended claim 1. Therefore, the additional references do not compensate for the noted deficiency in Huzinec's teaching.

Applicant also deny that sufficient motivation has been identified to support combination of the cited references. "To establish a prima facie case of obviousness based on a combination of the content of various references, there must be some teaching, suggestion or motivation in the prior art to make the *specific* combination that was made by the applicant." *In re Dance*, 160 F.3d 1339, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) (emphasis supplied). The motivation must have sufficient "force" to "impel persons skilled in the art to do what applicant has done." *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (BPAI 1993). Here, the asserted motivation of improving bacteriostatic properties would not have motivated one to modify the composition of

Huzinec's chewing gum because lemon oil was included not because of its bacteriostatic properties, but as a flavoring agent. The asserted motivation of varying the flavoring of a food composition also would not have impelled one to obtain lemon oil from the Novo lemons discussed by Kekelidze for use in Huzinec's chewing gum. An artisan from the field of food manufacture would not know that limonene is the only component of lemon oil responsible for flavoring; nor is it apparent that this is the case. Such an artisan would also likely be unaware of the limonene content of the lemons that he was using. In the circumstances, it is far more likely, an artisan minded to vary flavoring, would vary the amount of whatever lemon oil he had on hand in the chewing gum rather than scour the scientific literature in an attempt to identify the limonene content of Novo lemons. Thus, the asserted motivation of varying the flavoring of a food composition would not have compelled the artisan to the specific combination of elements represented by the present claims. For the above reasons, Applicant respectfully requests that the rejection be withdrawn.

35 U.S.C. § 103(a): Colodney and Kekelidze

The Examiner has rejected claims 1, 3 and 13 as obvious over Colodney in light of Kekelidze. Colodney is cited as disclosing an antibacterial dentifrice containing magnesium chloride, a cream or gel carrier and a flavoring oil, which may be a lemon oil. The Examiner acknowledges that Colodney does not disclose an embodiment in which both lemon oil and magnesium chloride are present. Kekelidze is cited as evidence that lemon oil intrinsically contains at least 70% monoterpenes. The Examiner says that one of ordinary skill in the art would have been motivated to have combined lemon oil into the claimed composition because lemon oil would have provided suitable flavoring to the dentifrice. This rejection is traversed insofar as it might be applied to the amended claims.

Colodney discusses a dentifrice containing a phosphate ion, a flavoring oil, and an antibacterial compound (1,6-di-(p-chlorophenyl biguanidohexane)). Colodney discusses the use of various metal salts as stabilizers of the dentifrice to avoid phase separation. The metal salts may contain alkaline earth metals such as magnesium and calcium, as well as halides such as chloride and bromide. The metal salts are included in a dentifrice to prevent the dentifrice from

separating into liquid and solid phases. Colodney also discusses the use of lemon oil as a possible flavoring oil. Colodney also refers 1,6-di-(p-chlorophenyl biguanido)hexane) as a preferred bacteriostatic agent. The present claims were not obvious over Colodney for similar reasons to those discussed in connection with Huzinec. That is, Colodney does not disclose or suggest an oral care composition that requires the inclusion of two or more salts selected from the group consisting of MgBr_2 , MgCl_2 , NaCl , KCl , and CaCl_2 , as recited by claim 1 as amended. Although Colodney discusses MgCl_2 and CaCl_2 , as well as the possibility of using bromide, Colodney discusses all of these components in the alternative as possible salts to include in the claimed method for the purpose of preventing phase separation. For example, no claims of Colodney recite including more than one salt in the composition. Instead, claim 1 recites the inclusion of "a water soluble alkaline earth metal of a strong acid to prevent phase separation." Dependent claims 4 and 5 of Colodney recite wherein the water soluble alkaline earth metal is calcium chloride or magnesium chloride, respectively.

Colodney would not have provided any motivation to use more than one salt because Colodney provides no indication that the presence of more than one salt is advantageous to prevent phase separation or otherwise. The purpose of Colodney's invention, as recited in the preamble of claim 1 of Colodney, is to prevent phase separation. Phase separation can be prevented by incorporating into the dentifrice a minor amount of a water soluble alkaline earth metal salt (column 5, lines 3-15). Although Colodney recites a plurality of possible components of the salts that can prevent phase separation, there is no suggestion that adding more than one of such salts would improve the phase separation characteristics of the dentifrice. Colodney also provides no other reason that the presence of multiple salts would be beneficial. Colodney discusses only 1,6-di(p-chlorophenyl biguanido) hexane and related molecules as the antibacterial agent (see column 3, lines 46-64), and provides no indication that any of the salts recited in claim 1 have or contribute to bacteriostatic activity. For these reasons, Colodney provides no motivation to use more than one salt recited in claim 1.

Kekelidze was cited only with respect to the monoterpene content of lemon oil and provides no teaching relevant to the requirement of multiple salts.

For these reasons, it is respectfully submitted that the rejection be withdrawn.

35 U.S.C. § 103(a): Colodney, Delli Santi and Kekelidze

The Examiner has rejected claims 1-9 and 13-15 under 35 U.S.C. § 103(a) as unpatenable over Colodney in view of Delli Santi and Kekelidze. Colodney is applied as above. The Examiner acknowledges that Colodney does not teach lemon oil in which limonene is present in at least 60%. Delli Santi and Kekelidze are applied as above. The Examiner says that one of ordinary skill in the art would have been motivated to have substituted the lemon oil flavoring disclosed by Colodney for the Novo lemon oil disclosed in Kekelidze for the benefit of improved flavoring and antibacterial activity.

As discussed in the previous section, Colodney does not disclose or provide motivation to add more than one salt to an oral care composition. Neither of the additional references compensate for this deficiency. Delli Santi does not disclose an oral care composition that includes any of the salts recited in claim 1. Kekelidze does not disclose any salts or oral care compositions. Therefore, the present claims would not have been obvious over the combination of cited references.

Further, it is submitted that insufficient motivation has been identified for combination of the references for the same reasons as discussed in connection with Huzinec in view of Delli Santi and Kekelidze. In brief, Delli Santi used lemon oil as a flavoring agent, not as a bacteriostatic agent. A different compound was included as a bacteriostatic agent. Therefore, the asserted motivation relating to bacteriostatic effects would not have motivated one to modify the lemon oil in Delli Santi's composition. Further, insofar as the artisan wanted to vary flavoring of Delli Santi's composition, he would be much more likely to do it by varying the amount of lemon oil he was already using, rather than by selecting Novo lemons for their high content of limonene.

For these reasons, withdrawal of the rejection is respectfully requested.

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PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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